IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION This Document Relates To: *All Actions*	Hon. Robert. B. Kugler Civ. No. 19-2875 (RBK/JS)

PLAINTIFFS' NOTICE OF VIDEOTAPED DEPOSITION TO API AND FINISHED DOSE MANUFACTURERS REGARDING LOSARTAN AND/OR IRBESARTAN ECONOMIC LOSS CLAIMS PURSUANT TO FED. R. CIV. P. 30(b)(6)

TO:

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PLEASE TAKE NOTICE that, pursuant to Fed. R. Civ. P. 30(b)(6), Plaintiffs will take the deposition upon oral examination of one or more designated corporate representatives with regard to the topics set forth on Exhibit A attached hereto. The deposition(s) will commence on a date to be determined, at 9:00 a.m., at a location to be determined, and continue from day to day as needed.

The deposition(s) will be taken upon oral examination before an officer authorized to administer oaths and will continue from day to day, until completed. Testimony given during the deposition will be recorded by sound video recording and stenographic means.

DATED this 22nd day of May, 2023.

MAZIE SLATER KATZ & FREEMAN, LLC

By: /s/ *Adam M. Slater*

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CERTIFICATE OF SERVICE

I, Marlene J. Goldenberg, hereby certify that on May 22, 2023, I caused true and correct copies of the foregoing to be transmitted via ECF to all counsel having registered an appearance on ECF, with courtesy copies served on counsel for Defendants, and Defendants' liaison counsel, via email.

DATED this 22nd day of May, 2023.

NIGH GOLDENBERG RASO & VAUGHN PLLC

By: /s/ *Marlene J. Goldenberg*

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EXHIBIT A

"You," "your" or "defendant" shall be used interchangeably and refers to the parties to which these requests are directed.

All references to the API are defined to include the irbesartan and/or losartan API manufactured, sold, or distributed by You or the entity(ies) from whom you purchased or acquired API for use in Your Finished Dose losartan and/or irbesartan.

All references to the finished dose are defined to include the irbesartan and/or losartan finished dose manufactured, sold, or distributed by You.

All references to testing are defined to include testing capable of detecting impurities such as nitrosamines and contents of API or finished dose, and include but are not limited to the following:

- Gas Chromatography (GC)
- Gas Chromatography- Flame Ionization Detector (GC-FID)
- Gas Chromatography- Mass Spectrometry (GC-MS)
- Gas Chromatography- tandem Mass Spectrometry (GC-MS/MS)
- Gas Chromatography- Selective Ion Monitoring Mass Spectrometry (GC-SIM MS)
- Gas Chromatography- High Resolution Mass Spectrometry (GC-HRMS)
- Gas Chromatography- Atomic Emission Spectrometry (GC-AES)
- Gas Chromatography- Flame Photometric Detector (GC-FPD)
- Gas Chromatography- Nitrogen Phosphorus Detector (GC-NPD)
- Gas Chromatography- Thermal Conductivity Detector (GC-TCD)
- Gas Chromatography- Photoionization Detector (GC-PID)
- Gas Chromatography- Electrolytic Conductivity Detector (GC-ELCD)
- Headspace Gas Chromatography (HS-GS)
- Liquid Chromatography (LC)
- High Performance Liquid Chromatography (HPLC)
- Liquid Chromatography-Mass Spectrometry (LC-MS)
- Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS)
- Liquid Chromatography- Selective Ion Monitoring Mass Spectrometry (LC-SIM MS)
- Liquid Chromatography- High Resolution Mass Spectrometry (LC-HRMS)
- Atomic Absorption Spectroscopy (AAS)
- Atomic Emission Spectrometry (AES)

Testing of Losartan and Irbesartan API

1. The date on which the contamination or process which caused the contamination in Your API started.
2. The first time You knew or understood that its API might contain nitrosamines.
3. The cause of the contamination of Your API with nitrosamines including NDMA, NDEA, and/or NMBA.

4. The cause of the contamination of Your Finished Dose with nitrosamines including NDMA, NDEA, and/or NMBA.
5. Whether API or Finished Dose product past its retest or expiration date was tested, and why and how this choice was made.
6. Whether API or Finished Dose product that was untested was recalled, and why and how this choice was made..
7. The root cause investigation for the nitrosamine impurities, including NDMA, NDEA, and/or NMBA in the Your API.
8. The root cause investigation for the nitrosamine impurities, including NDMA, NDEA, and/or NMBA in the Your finished dose.
9. The testing results for all testing by You, Your agents, or any other person or entity that is known to Your of Your API.
10. The testing results for all testing by You, Your agents, or any other person or entity that is known to Your or Your finished dose.
11. The testing results for all testing by You, Your agents, or any other person or entity that is known to Your regarding the solvents utilized in the manufacture of Your API.
12. The testing results for all testing by You, Your agents, or any other person or entity that is known to Your regarding the solvents utilized in the manufacture of Your Finished Dose.
13. The testing results for all testing by You, Your agents, or any other person or entity that is known to Your regarding the production equipment utilized in the manufacture of Your API.
14. The testing results for all testing by You, its agents, or any other person or entity that is known to You of the production equipment utilized in the manufacture of Your finished dose.
15. The extent of the nitrosamine contamination of Your API and finished dose sold in the United States, both in terms of the concentration per pill, and across all of the lots/batches.

Quality Assurance and Quality Control Activities

16. Your SOP's/policies/procedures intended to prevent, detect, or act in response to any impurity or contamination of Your API.
17. Your SOP's/policies/procedures intended to prevent, detect, or act in response to any impurity or contamination of Your Finished Dose.
18. Your application of and/or compliance with cGMPs in connection with the manufacture of Your API.
19. Your application of and/or compliance with cGMPs in connection with the manufacture of Your Finished Dose.
20. The deviation reports, deviation investigation, or related report detailing what went wrong generated or received by You relating to Your API.
21. The deviation reports generated or received by You relating to Your Finished Dose.
22. All CAPAs relating in any way to nitrosamines contamination in Your losartan or irbesartan API or Finished Dose.

Process Development

23. Any modifications with regard to the manufacturing process for Your API or Finished Dose, including: (1) the reasons for the modifications, (2) the testing and evaluation in connection with the modifications, and (3) the relationship between the modifications and the nitrosamine contamination of Your API or Finished Dose.
24. Any evaluation or risk assessment conducted by or on Your behalf with regard to the manufacturing process(es) for Your API or Finished Dose.
25. Your evaluation and knowledge of the risk of the creation of nitrosamines including NDMA, NDEA, and/or NMBA as a result of the manufacturing process for Your API.
26. Your evaluation and knowledge of the risk of the creation of nitrosamines including NDMA, NDEA, and/or NMBA as a result of the manufacturing process for Your Finished Dose.
27. Your evaluation and knowledge of the health risks of nitrosamines including NDMA, NDEA, and NMBA, including but not limited to as an impurity or contaminant of Your API and/or finished dose.

Communications with Regulatory Agencies

28. The communications with any regulatory authority, including but not limited to the FDA, with regard to the manufacturing process for Your API, and/or any modifications to the manufacturing process for Your API.
29. The communications with any regulatory authority, including but not limited to the FDA, with regard to the manufacturing process for Your finished dose, and/or any modifications to the manufacturing process for Your Finished Dose.
30. Your disclosures to regulatory authorities, including the FDA, with regard to the actual or potential contamination of Your API or Finished Dose with nitrosamines including NDMA, NDEA, or NMBA.
31. Your filings with regulatory authorities, including the FDA, regarding the manufacturing process, and any manufacturing process changes, for Your API or Finished Dose including in ANDA and Drug Master File filings and supplements.

Your Communications with API and Finished Dose Customers and Downstream Customers

32. Your oral and written communications with any person or entity, including but not limited to Your API and Finished Dose customers, with regard to the manufacturing process, and any changes to the manufacturing process, for Your API.
33. Your oral and written communications with any person or entity, including but not limited to Your API and finished dose customers, with regard to the manufacturing process, and any changes to the manufacturing process, for Your Finished Dose.
34. Your oral and written communications with its API Customers or other downstream entities (i.e. wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the Your API.
35. Your oral and written communications with its finished dose customers or other downstream entities (i.e., wholesalers, retailers, consumers, TPP's) regarding quality, purity, or contamination issues related to the Your Finished Dose.

36. Your oral and written statements (defined to include representations and warranties) to finished dose manufacturers, repackagers, relabelers, wholesalers, retailers, and consumers with regard to the contents, quality, and purity of Your API.
37. Your oral and written statements (defined to include representations and warranties) to finished dose manufacturers, repackagers, relabelers, wholesalers, retailers, and consumers with regard to the contents, quality, and purity of Your Finished Dose.
38. Your product recall for Your API including who communicated with, how, about what, and the retention of recalled or sequestered API.
39. Your product recall for Your Finished Dose, including who You communicated with, how, about what, and the retention of recalled or sequestered finished dose.
40. All credits, indemnification, refunds, and/or penalties paid or provided by or to You in connection with the nitrosamine contamination of Your API.
41. All credits, indemnification, refunds, and/or penalties paid or provided by or to You in connection with the nitrosamine contamination of Your finished dose.

Compliance with cGMPs

42. Your compliance or non-compliance with cGMPs as it relates to the manufacture, quality assurance, quality control, and sale of Your API and finished dose.

Product Tracing

43. The identity of all lots and batches of API which contained any amount of nitrosamines, and the nitrosamine levels for each batch.
44. The identity of all lots and batches of Finished Dose product which contained any amount of nitrosamines, and the nitrosamine levels for each batch.
45. How to match up each lot of API which contained any amount of nitrosamines to each Finished Dose pill manufactured from that lot or batch.
46. Tracing of batches and lots of Your API sold downstream and ultimately intended for use by consumers in the United States.
47. Tracing of batches and lots of Your finished dose sold downstream and ultimately intended for use by consumers in the United States.
48. The pricing of Your API that was ultimately sold in the United States, at each level of the supply chain.
49. The pricing of Your finished dose, per pill and per quantity, that was ultimately sold in the United States, at each level of the supply chain.
50. The gross and net profits to You from the sale of Your API in or for sale in the United States.
51. The gross and net profits to You from the sale of Your finished dose in the United States.
52. The quantity/units including pill counts of Your API sold in the United States.
53. The quantity/units including pill counts of Your API sold in the United States, and recalled or returned.
54. The quantity/units including pill counts of Your finished dose sold in the United States.
55. The quantity/units including pill counts of Your finished dose sold in the United States, and recalled and returned pills.

56. Your API sales and pricing data produced by you in this litigation (sample documents to be provided ahead of deposition during meet and confer process).
57. Your finished dose sales and pricing data produced by you in this litigation (sample documents to be provided ahead of deposition during meet and confer process).